

**In The Matter Of:**

***ELI LILLY AND COMPANY, and IMCLONE SYSTEMS  
LLC***

*v.*

***GENENTECH, INC. and CITY OF HOPE***

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***SIR GREGORY WINTER - Vol. 1***

***January 19, 2015***

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**Mylan v. Genentech  
IPR2016-00710**



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25

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18 Exhibit 4 United States Patent .....109  
No.: 4,816,567, March 28, 1989  
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20 Exhibit 5 United States Patent .....137  
No.: 5,225,539, July 6, 1993  
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1 PROCEEDINGS  
2 THE VIDEOGRAPHER: This is the video operator,  
3 Wendy Viner, of Merrill Legal Solutions. Today's date is  
4 January 19, 2015 and the time is 10:05 a.m. We're at  
5 Trinity College, Cambridge, U.K., to take the videotaped  
6 deposition of Sir Gregory Winter in the matter of Eli Lilly  
7 & Company et al versus Genentech and City of Hope, case  
8 number 2:13-cv-07248-MRP-JEMx.  
9 The court reporter today is Chanelle Malliff of  
10 Merrill Legal Solutions. Would the court reporter please  
11 swear in the witness.  
12 SIR GREGORY WINTER  
13 having been sworn testified as follows:  
14 THE VIDEOGRAPHER: Would counsel please identify  
15 themselves and state whom they represent and we can proceed.  
16 MS. DURIE: Daralyn Durie, representing Genentech.  
17 MR. BRAUSA: Adam Brausa, representing Genentech.  
18 MS. HELM: Katherine Helm, representing Eli Lilly.  
19 MR. SCHWARTZ: Robert Schwartz, representing  
20 Eli Lilly, and with me are my colleagues Brendan O'Malley.  
21 And from Lilly, Mark Stewart.  
22 THE VIDEOGRAPHER: Thank you. Please proceed.  
23 EXAMINATION BY MS. DURIE:  
24 Q. Good morning.  
25 A. Good morning.

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1 Q. How would you like me to address you this morning?  
2 A. You can call me Greg.  
3 Q. Very good.  
4 A. If you get nasty you can call me Sir Gregory.  
5 Q. You have expressed certain opinions in this case  
6 regarding the Cabilly family of patents; is that right?  
7 A. That's right.  
8 Q. And one of the opinions that you have expressed  
9 concerns the written description requirement?  
10 A. Yep.  
11 Q. What is your understanding of the written  
12 description requirement?  
13 A. So my understanding was put down in my deposition  
14 but essentially my understanding is that the written  
15 description should be sufficient to guide somebody to be  
16 able to do the work described in it.  
17 Q. You've also expressed opinions in this case  
18 regarding the enablement requirement; is that right?  
19 A. That's correct.  
20 Q. What do you understand the difference to be between  
21 the written description requirement and the enablement  
22 requirement, if any?  
23 MS. HELM: Objection: calls for a legal  
24 conclusion.  
25 A. I had taken them to be very similar but what

<p style="text-align: right;">Page 6</p> <p>1 I would like to do would be to refer to my deposition where 2 I think I do deal with those two points. 3 BY MS. DURIE: 4 <b>Q. Sure. Let me have marked as the first exhibit a 5 copy of the expert report of Sir Gregory Winter. 6 (Exhibit 1 marked for identification.)</b> 7 A. So in page 4, 20 it explains: 8 "... specification must provide adequate written 9 description of the invention ..." 10 And it must explain how to use the invention, clear 11 language. That's written description. And the enablement 12 issue or the enablement requirement is when a person at the 13 time of invention would, on looking at that, be able to 14 practice the invention. 15 <b>Q. Is there any difference in your mind between the 16 written description requirement and the enablement 17 requirement?</b> 18 MS. HELM: Objection. 19 A. Is there what, sorry? 20 BY MS. DURIE: 21 <b>Q. Is there any difference in your mind between the 22 written description requirement and the enablement 23 requirement?</b> 24 MS. HELM: Objection: calls for a legal 25 conclusion.</p>	<p style="text-align: right;">Page 8</p> <p>1 A. I would say it teaches and provides guidance in 2 combination with other prior art. 3 <b>Q. And so your understanding is that you can look to 4 other prior art as well as what is written down in the 5 patent itself to assess compliance with the written 6 description requirement?</b> 7 A. Sorry, can you repeat that again? 8 <b>Q. Sure. So is it your understanding that you can 9 look at other prior art as well as what is written within 10 the patent itself to assess compliance with the written 11 description requirement?</b> 12 MS. HELM: Objection. I object to this entire 13 line of questioning as calling for legal conclusions. 14 A. So what does that mean? 15 MS. HELM: You still need to answer the question. 16 I'm objecting as to the form. 17 A. The form of the -- 18 MS. HELM: For calling for legal conclusions. 19 A. Can you repeat that question again, sorry? 20 BY MS. DURIE: 21 <b>Q. Sure. Is it your understanding then that you can 22 look to other prior art as well as what is written within 23 the patent itself in order to assess compliance with the 24 written description requirement?</b> 25 MS. HELM: Same objection.</p>
<p style="text-align: right;">Page 7</p> <p>1 A. My understanding had been that the written 2 description essentially was what was written down; in other 3 words, whether that is adequate on what's written down. And 4 there are other factors come into enablement. 5 BY MS. DURIE: 6 <b>Q. What are the additional factors that come into 7 enablement?</b> 8 A. Well, I understand it would relate to the factors 9 whether for example considering whether undue 10 experimentation might be required in order for somebody to 11 do that work. So the written description and enablement are 12 very similar concepts but obviously written description is 13 what is written. Enablement I took to be beyond the written 14 description, plus. That was my interpretation. 15 <b>Q. Does the written description requirement as you 16 have applied it require that what is written down teach a 17 person of skill in the art how to practice the invention?</b> 18 MS. HELM: Objection: calls for a legal 19 conclusion. 20 A. Sorry, could you repeat that? 21 BY MS. DURIE: 22 <b>Q. Sure. Does the written description requirement as 23 you have applied it require that what is written down teach 24 a person of ordinary skill in the art how to practice the 25 invention?</b></p>	<p style="text-align: right;">Page 9</p> <p>1 A. My understanding would be that that is the way that 2 I have looked at this. Whether that is true, I don't know. 3 BY MS. DURIE: 4 <b>Q. Do you agree that compliance with the written 5 description requirement is tested relative to claim 6 limitations?</b> 7 MS. HELM: Objection: calls for a legal conclusion 8 and outside the scope of his report. 9 A. And can you repeat that question again? 10 BY MS. DURIE: 11 <b>Q. Sure. Do you agree that compliance with the 12 written description requirement is tested relative to the 13 limitations of a claim?</b> 14 A. I don't understand the question. 15 <b>Q. Fair enough. Let me have marked as the next 16 exhibit a copy of U.S. patent 6,331,415. 17 (Exhibit 2 marked for identification.)</b> 18 <b>Do you recognize what I have put in front of you 19 as one of the Cabilly patents that is at issue in this 20 litigation?</b> 21 A. Yes, I do. 22 <b>Q. And if I refer to this patent, the '415 patent, as 23 the Cabilly 2 patent, will you understand what I'm 24 referring to?</b> 25 A. Yes, I do.</p>

<p style="text-align: right;">Page 10</p> <p>1 <b>Q. Now when you conducted your analysis of compliance</b>  2 <b>with the written description requirement with respect to the</b>  3 <b>Cabilly 2 patent, how did you go about that analysis?</b>  4 A. When I looked at the compliance of this for a  5 written description?  6 <b>Q. Yes.</b>  7 MS. HELM: Objection: vague. The witness may  8 refer to his report.  9 A. Well, what I looked at was the claims on the patent  10 and I looked at what those claims said and I looked at what  11 was done in the patent and I looked at what one could  12 reasonably infer at the time from prior art. So that's the  13 essence of what I did.  14 BY MS. DURIE:  15 <b>Q. So if in the patent you turn for example to</b>  16 <b>claim 33, which should appear at the back of the patent.</b>  17 <b>You undertook an analysis of whether the description of the</b>  18 <b>Cabilly 2 patent provides an adequate written description</b>  19 <b>for claim 33; is that right?</b>  20 A. Yep.  21 <b>Q. Have you heard of the term "the limitations of a</b>  22 <b>claim"?</b>  23 A. I've heard of the term but I could probably do with  24 some instruction on what it means if I'm going to be quizzed  25 on it.</p>	<p style="text-align: right;">Page 12</p> <p>1 <b>said first and second DNA sequences."</b>  2 <b>Do you understand claim 33 of the Cabilly 2 patent</b>  3 <b>to require the co-expression of at least the variable domain</b>  4 <b>of a heavy chain and the variable domain of a light chain in</b>  5 <b>a single host cell?</b>  6 MS. HELM: Objection: calls for a legal  7 conclusion.  8 A. Sorry, can you repeat that question again?  9 BY MS. DURIE:  10 <b>Q. Sure. Do you understand claim 33 of the Cabilly 2</b>  11 <b>patent to require the co-expression of at least the variable</b>  12 <b>domain of a heavy chain and the variable domain of a light</b>  13 <b>chain in a single host cell?</b>  14 MS. HELM: Same objection.  15 A. I took it that this claim covers a molecule which  16 is an immunoglobulin molecule or in fact an immunologically  17 functional molecule which would have heavy and light chains  18 within it. That's what I had considered and I believe this  19 does describe such a molecule. Whether it requires it, I'd  20 have to think very carefully about the language of this, and  21 whether it might allow the production of a single -- one of  22 those as a single domain. And I don't believe it does but  23 I think at the moment it is essentially describing -- it  24 would certainly cover the variable domain of a heavy and  25 light in the same associated fragment.</p>
<p style="text-align: right;">Page 11</p> <p>1 <b>Q. Fair enough. If I were to refer to the</b>  2 <b>requirements of a claim would you understand what I'm</b>  3 <b>referring to?</b>  4 A. The key features of the claim.  5 <b>Q. Did you undertake your written description analysis</b>  6 <b>by focusing on the requirements of the claim?</b>  7 MS. HELM: Objection: calls for a legal  8 conclusion.  9 A. Essentially I'm a scientist so what I did is  10 I looked at this and I said: what does this describe?  11 BY MS. DURIE:  12 <b>Q. If we take a look at claim 33 and we see it's:</b>  13 <b>"A process for producing an immunoglobulin molecule or</b>  14 <b>an immunologically functional immunoglobulin fragment</b>  15 <b>comprising at least the variable domains of the</b>  16 <b>immunoglobulin heavy and light chains, in a single host</b>  17 <b>cell, comprising:"</b>  18 <b>And then it says:</b>  19 <b>"independently expressing a first DNA</b>  20 <b>sequence encoding at least the variable domain of the</b>  21 <b>immunoglobulin heavy chain and a second DNA sequence</b>  22 <b>encoding at least the variable domain of the</b>  23 <b>immunoglobulin light chain so that said immunoglobulin</b>  24 <b>heavy and light chains are produced as separate</b>  25 <b>molecules in said single host cell transformed with</b></p>	<p style="text-align: right;">Page 13</p> <p>1 BY MS. DURIE:  2 <b>Q. For purposes of assessing compliance with a written</b>  3 <b>description requirement, have you focused in your analysis</b>  4 <b>on what the claim covers?</b>  5 MS. HELM: Objection: calls for a legal conclusion  6 and asked and answered.  7 A. So what do I have to do? So I've answered it.  8 MS. DURIE: You can still answer the question.  9 Lilly's attorney can make objections for the record but  10 you're still required to answer my questions.  11 THE WITNESS: So can you repeat the question  12 again?  13 BY MS. DURIE:  14 <b>Q. Of course. For purposes of assessing compliance</b>  15 <b>with a written description requirement, have you then</b>  16 <b>focused on what the claim covers?</b>  17 MS. HELM: Same objection.  18 A. I have focused on the fact that this claim covers  19 two associated domains. That's what I focused on. I have  20 not thought about other possibilities and I am not entirely  21 sure whether they're there because I need to think about the  22 claim carefully.  23 BY MS. DURIE:  24 <b>Q. When you say "covers", what do you mean by that?</b>  25 A. Well I would mean that if you made a molecule, that</p>

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